

REMARKS

This response is prepared in substantially the same order as the issues appear in the Office Action dated June 03, 2004.

Claim Rejections - 35 USC §112 First Paragraph

Claims 1, 3, 9, 14, 15 and 20 are rejected as being non-enabling under 35 USC §112 first paragraph over the term "CHO-derived cell line."

Claims 3 and 14 are withdrawn.

Claims 1 and 20 have been amended to use the language "consisting of." Claim 15 is amended to depend from Claim 10, which now has incorporated the limitations of the withdrawn Claim 14.

Accordingly, these amendments should overcome the ground of the rejections of Claims 1, 9, 15 and 20.

Claim Rejections - 35 USC §102 (a)

Claims 1, 2, 6-8, 10-13 are rejected under 103(a) as being anticipated by Cox *et al.*, (WO 01/03737, hereinafter *Cox*).

Claim 10 is withdrawn.

For the following reasons and analyses, Applicants respectfully traverse the Examiner's basis for and conclusion of the rejections.

I. Legal Standard

The initial burden is on the Patent and Trademark Office to establish a *prima facie* case of anticipation. *See MPEP* §2112.

"Anticipation requires the disclosure in a single prior art reference of each element of the claim under consideration." *W. L. Gore & Associates v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984), emphases added. *Accord, Celeritas Techs. Ltd. v. Rockwell Int'l Corp.*, 150 F.3d 1354, 1360, 47 USPQ2d 1516, 1522 (Fed. Cir. 1998); *Dayco Prods., Inc. v. Total Containment, Inc.*, 329 F.3d 1358, 1368 (Fed. Cir. 2003). *See Also MPEP* §2131.

In addition, the prior art reference must be enabling. *See for example, Akzo N. V. v. U. S. Int'l Trade Commission*, 808 F.2d 1471, 1 USPQ2d 1241, 1245 (Fed. Cir. 1986) (citing *In re Brown*, 329 F.2d 1006, 1011, 141 USPQ 245, 249 (CCPA 1964)). *Accord, Crown Operations International, Ltd. v. Solutia Inc.*, 289 F.3d 1367, 1375, 62 USPQ2d 1917, 1921 (Fed. Cir. 2002).

Inherent anticipation requires that the missing descriptive material is "necessarily present," not merely probably or possibly present, in the prior art. *See In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999) (citing *Continental Can Co. USA, Inc. v. Monsanto Co.*, 948 F.2d 1264, 1268, 20 USPQ2d 1746, 1749 (Fed. Cir. 1991))

II. **Analysis**

Applicants will discuss independent claims, Claims 1 and 10, first.

CLAIM 1

Claim 1 has been amended to include the limitations in Claim 3. Accordingly, there is no unity between *Cox* and the amended Claim 1 of Applicants' invention. Therefore, *Cox* cannot anticipate, *prima facie*, Claim 1.

CLAIM 10

Regarding Claim 10, the Examiner concedes that *Cox* does not explicitly that a recombinant fusion protein "exhibits an enhanced *in vitro* biological activity of at least 2 fold relative to that of rHuEPO on a molar basis" as claimed. In addition, the Examiner does not point to anywhere in *Cox* that teaches or discloses expressly "... (b) growing the cell line under conditions the recombinant protein is expressed in its growth medium in excess of 10 µg per million cells in a 24 hour period ..." Since the Examiner has not explained how or why this limitation is "necessarily present," not merely probably or possibly present, in the prior art, *In re Robertson*, Applicants respectfully submit that the Examiner has not carried her burden to prove anticipation. There is no unity, thus *Cox* cannot anticipate, *prima facie*, Claim 10 of this application.

In addition, Applicants respectfully submit that the Examiner's reliance on *In re Papesch* is misplaced. Applicants submit that *Cox* is not enabling with respect to the claimed

recombinant fusion protein to anticipate the invention. *Cox* merely mentions many many possibilities. The Examiner has not pointed to anywhere in *Cox* where the specific combination of the claimed recombinant fusion protein can be made specifically by the claimed method. Without demonstrating that *Cox* has disclosed the same “compound,” Applicants respectfully submit that the Examiner cannot rely on *Papesch* to support the rejection, even *assuming* that the biological activity limitation in Claim 10 is a missing element in *Cox*. Of course, this is not the case. (See the last full paragraph of the preceding page regard step (b) of Claim 10).

Nonetheless, in order to move the application forward, Applicants have made additional amendments to Claim 10 by incorporating the limitations of Claim 14 into Claim 10. Applicants note that the Examiner indicates Claims 14 and 15 are not anticipated by *Cox*. Claim 14 is withdrawn. Claim 15 is amended to depend from Claim 10 directly because Claim 14 is withdrawn herein.

Because Claims 2, 6-8, and 11-13 depend from Claim 1 and Claim 10 respectively and they contain additional and more stringent limitations, they are not anticipated by *Cox* either.

III. Conclusion regarding 102 rejections

For the foregoing reasons, Applicants respectfully submit that *Cox* does not anticipate the claimed inventions of Claims 1, 2, 6-8, and 11-13 as they are currently amended. Accordingly, Applicants respectfully request that the Examiner reconsider and withdraw the rejections of Claims 1, 2, 6-8, and 11-13.

Conclusion

No new matter is introduced into the application by any and all of the amendments made herein to the claims. All the amendments to the claims are supported by the disclosure of the originally filed application. Applicants respectfully request that the Commissioner enter these Amendments into the application as submitted herein.

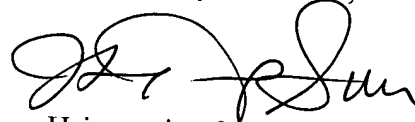
Applicants believe that they have discussed all the aspects of the issues raised in the Office Action and respectfully submit that (A) the amendments overcome the §112 first paragraph rejections; and (B) the Examiner has not carried the burden to prove the ground for rejecting the claims under §102(a) or in the alternative, the amendments to Claim 10 overcome the ground of such a rejection.

Claims 3 and 14 are withdrawn from consideration. All of the other elected claims, Claims 1, 2, 6-13, 15 and 20, are now allowable in their currently amended form. An early and favorable action is respectfully solicited.

If the Examiner wishes to discuss additional claim amendments to place the application in better form for allowance or any other issues related to this application, the undersigned attorney may be reached at the phone numbers, and mailing address herein below.

Applicants believe that no fee is due. However, the Commissioner is hereby authorized to charge any additional/overlooked fees or credit any overpayments to Deposit Account No. 50-2980 maintained by The SUN Law Office PLLC.

Respectfully submitted,



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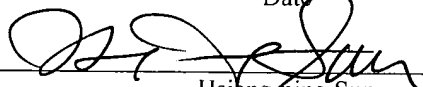
July 26, 2004

**CERTIFICATE OF MAILING**

I hereby certify that this correspondence is being deposited with the United States Postal Service as express mail in an envelope addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on

July 26, 2004

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Hsiangning Sun

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